

**UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK**

3B MEDICAL, INC.,

Plaintiff,

v.

SOCLEAN, INC.,

Defendant.

No. 1:19-cv-03545

JURY TRIAL DEMANDED

AMENDED COMPLAINT

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Plaintiff 3B Medical, Inc. (“3B”) alleges as follows against Defendant SoClean, Inc. (“SoClean”):

NATURE OF THE ACTION

1. This is an action for false advertising under Section 43(a) of the Lanham Act, 15 U.S.C. § 1125(a) and for related violations of New York state law.

2. 3B and SoClean are competitors in the market for devices that automatically sanitize continuous positive airway pressure (“CPAP”) machines, which treat sleep apnea and other illnesses. Since approximately 2012, SoClean has used false and misleading representations about its devices to market the SoClean 2 CPAP Sanitizing Machine, the SoClean 2 Go CPAP Sanitizing machine, and their predecessor devices (collectively “the SoClean devices”). The SoClean devices work by generating ozone to sterilize and deodorize CPAP machines. Ozone (O₃) is an unstable toxic gas with a pungent characteristic odor—sometimes described as “clean” smelling—that can kill bacteria and viruses. To be effective as a germicide, ozone must be present in a concentration far greater than can be safely tolerated by people or animals.

3. Various SoClean marketing materials fail to disclose that its devices emit ozone, which is a longstanding requirement of federal law. Instead, SoClean falsely represents that its devices use “activated oxygen” to clean CPAP machines. SoClean markets the devices as “safe” and “healthy,” which is false given that they generate toxic ozone gas at levels that substantially exceed federal regulations. SoClean falsely represents that its devices use no “chemicals” or “harsh chemicals” to clean CPAP machines, despite using ozone gas—a harsh chemical that causes respiratory problems in humans. SoClean represents that its devices use the same sanitizing process found in “hospital sanitizing,” however, hospitals cannot and do not use ozone sanitizers in spaces occupied by patients. SoClean also claims that separately sold filters convert “activated oxygen” into “regular oxygen,” which is false because SoClean’s filters have no measurable effect

on the device's ozone output. Finally, SoClean falsely claims that its devices are "sealed" such that "activated oxygen" (*i.e.*, ozone) does not escape the devices.

4. SoClean's representations are designed to mislead consumers into believing that the machine uses a benign form of oxygen to clean CPAP machines rather than a harsh gas that is generally only suitable for commercial sanitization under highly controlled conditions. These misrepresentations are made more egregious because the SoClean devices are designed and marketed for use on the consumer's bedside table and because CPAP users suffer from many symptoms that ozone exposure exacerbates—making the falsehoods especially reprehensible and dangerous.

5. SoClean's misrepresentations have allowed it to command a market share of ninety percent. Due to the nature of SoClean's business, its customers all have breathing problems for which they are receiving medical treatment in the form of CPAP therapy. If CPAP users knew that the SoClean devices generate unsafe levels of toxic gas, which is then pumped into their CPAP machines and into their bedrooms, they would find this risk material to their purchasing decisions. Consumers who manage to learn about SoClean's ozone use often purchase 3B's products, which are the only devices in the market that do not operate using ozone gas. Because of this, SoClean's prolific false advertising leads consumers to purchase SoClean's products when they would otherwise purchase 3B's.

PARTIES

6. Plaintiff 3B Medical, Inc. is a Florida corporation with its principal place of business in Winter Haven, Florida.

7. Defendant SoClean Inc. is a Delaware corporation with its principle place of business at 12 Vose Farm Road, Peterborough, New Hampshire 03458.

JURISDICTION & VENUE

8. Subject Matter Jurisdiction. The Court has subject matter jurisdiction pursuant to 28 U.S.C. § 1331 because this action arises under the Lanham Act, 15 U.S.C. § 1121. The Court also has supplemental jurisdiction over 3B's state law claims pursuant to 28 U.S.C. § 1367(a). In addition, the Court has jurisdiction pursuant to 28 U.S.C. § 1332(a) because the amount in controversy exceeds \$75,000 and 3B and SoClean are citizens of different states—Florida and New Hampshire, respectively.

9. Personal Jurisdiction. The Court has personal jurisdiction over SoClean because SoClean regularly conducts business in New York State and because SoClean has falsely advertised the product to the 19.5 million consumers who reside in New York State, including the 5.2 million consumers who reside in the Southern District of New York. SoClean has also sold its products in New York State, including in the Southern District of New York. In addition, SoClean committed tortious acts in New York State, including in the Southern District of New York, and 3B's claims arise out of such acts, and/or because SoClean has otherwise made or established contacts in New York State, including the Southern District of New York, sufficient to permit the exercise of personal jurisdiction.

10. Venue. Venue is proper in this judicial district pursuant to 28 U.S.C. § 1391 because SoClean is subject to personal jurisdiction in this judicial district and because a substantial part of the events giving rise to the claims in this action occurred in this judicial district. Specifically, SoClean runs television, online, radio, text messaging, and print advertising campaigns to promote its products, which reach the more than 5.2 million consumers who reside in the Southern District of New York.

FACTUAL ALLEGATIONS

11. SoClean manufactures and sells medical devices that clean continuous positive

airway pressure (“CPAP”) machines.

12. 3B sells competing devices, the Lumin and the Lumin Bullet (collectively “the Lumin”) as part of its suite of products for people who suffer from sleep apnea.

A. The Market for CPAP Sanitizing Devices

13. The SoClean and Lumin devices are compatible with many brands of CPAP machines.

14. An estimated 28 million people in the United States use a CPAP machine.

15. A large percentage of CPAP users suffer from respiratory problems.

16. CPAP machines are most commonly prescribed for sleep apnea, a potentially serious disorder in which an individual’s breathing repeatedly stops and starts while sleeping. The most common form of sleep apnea is caused by airway obstruction.

17. CPAP machines are also used to treat diseases such as pulmonary fibrosis and Chronic Obstructive Pulmonary Disease (“COPD”), an umbrella term used to describe progressive lung diseases characterized by increasing breathlessness.

18. While sleeping, a CPAP user wears a face mask, which is attached by a hose to a machine that pressurizes air.



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19. Room air is drawn into the CPAP machine through an air intake and, once inside,

the machine pressurizes the air. *See* Ex. A (Airflow Diagrams), Figure 1.

20. The pressurized air is then pumped from the CPAP's air outtake, through a hose, and into the facemask, delivering just enough air pressure to keep the user's upper airway passages open while sleeping. *See* Ex. A (Airflow Diagrams), Figure 1.

21. Some CPAP machines also include a heated humidifier that is either fully integrated into the machine or easily attached. Use of the humidifier is optional; generally, it can either be turned off or detached.

22. Many CPAP users concerned with health and cleanliness are interested in regularly sanitizing or disinfecting their CPAP equipment without the time and hassle required for handwashing.

23. 3B meets this need through the Lumin, which uses a unique light—a UV-C light source—that has been proven to kill harmful bacteria, viruses, mold, and fungus. *See* Ex. B (Lumin Device Photos).

24. As of September 2019, a bundle containing the Lumin and Lumin Bullet retails for \$329.

25. SoClean has taken a different approach to the problem—the SoClean devices use ozone gas in an attempt to clean CPAP equipment.

26. The SoClean 2 and the SoClean 2 Go work similarly, but the SoClean 2 Go is a smaller, more portable version. *Compare* Ex. C (SoClean 2 Photos), *with* Ex. D (SoClean 2 Go Photos).

27. As of September 2019, the SoClean 2 retails for \$398.

28. Prior to its discontinuance in January 2019, the SoClean 2 Go retailed for around \$250.

29. The SoClean devices are Class I medical devices subject to the Medical Device Amendments to the Food, Drug and Cosmetic Act (“FDCA”) and the implementing regulations promulgated by the Food and Drug Administration (“FDA”).

30. As Class I medical devices, the SoClean devices are not subject to premarket review by the FDA.

B. FDA Regulation of Ozone

31. All medical devices must comply with the FDA’s Maximum Acceptable Level of Ozone Rule, 21 C.F.R. § 801.415 (2019).

32. The FDA’s Maximum Acceptable Level of Ozone requirements took effect in 1974. *See* FDA Final Rulemaking: Ozone Generators and Other Devices Generating Ozone, 39 Fed. Reg. 13773-74 (Apr. 17, 1974).

33. The FDA has determined that “[o]zone is a toxic gas.” 21 C.F.R. § 801.415(a).

34. The FDA initially regulated ozone in medical devices because “[i]n order for it to be effective as a germicide, ozone must be present in a concentration far greater than that which can be safely tolerated by man and animals.” FDA Notice of Proposed Rulemaking, 37 Fed. Reg. 12644 (June 27, 1972); *accord* 21 C.F.R. § 801.415(a) (same).

35. The FDA found that “in tests conducted to study the bactericidal properties of ozone, test animals have died before the bacteria were completely destroyed.” FDA Notice of Proposed Rulemaking, 37 Fed. Reg. 12644 (June 27, 1972).

36. The FDA has determined that ozone exposure causes “undesirable physiological effects on the central nervous system, heart, and vision” and “the predominant physiological effect of ozone is primary irritation of the mucous membranes. Inhalation of ozone can cause sufficient irritation to the lungs to result in pulmonary edema.” 21 C.F.R. § 801.415(b).

37. FDA regulations make it illegal for a medical device to “generate[] ozone at a level

in excess of 0.05 part per million by volume of air circulating through the device” 21 C.F.R. § 801.415(c)(1).

38. FDA regulations make it illegal for a medical device to “cause[] an accumulation of ozone in excess of 0.05 part per million by volume of air . . . in the atmosphere of enclosed space intended to be occupied by people for extended periods of time, e.g., houses, apartments, hospitals, and offices.” 21 C.F.R. § 801.415(c)(1).

39. FDA regulations make it illegal for a medical device to “generate ozone and release it into the atmosphere in hospitals or other establishments occupied by the ill or infirm.” 21 C.F.R. § 801.415(c)(2).

40. FDA regulations make it illegal for a medical device “[t]o generate ozone and release it into the atmosphere and does not indicate in its labeling the maximum acceptable concentration of ozone which may be generated (not to exceed 0.05 part per million by volume of air circulating through the device) as established herein and the smallest area in which such device can be used so as not to produce an ozone accumulation in excess of 0.05 part per million.” 21 C.F.R. § 801.415(c)(3).

C. The Facts About Ozone Gas

41. Ozone (O₃) is an unstable blue gas with a pungent characteristic odor.

42. Ozone gas forms when oxygen molecules (O₂) interact with electricity and recombine with oxygen atoms (O) to form ozone (O₃).¹

43. Because ozone is an unstable gas, over time it gradually breaks down by recombining with other molecules to re-form oxygen (O₂).

¹ Oxygen atoms (the “O” on the periodic table of elements) and oxygen molecules (the O₂ that we breathe) are both commonly called oxygen.

44. In still air at room temperature, studies show it can take up to twenty-five hours for ozone levels to reduce by half,² and ozone continues to break down at this rate until it dissipates.

45. When ozone encounters organic material, its third oxygen atom can detach from the ozone molecule and re-attach to molecules of the other substance, thereby altering the chemical composition of the other substance.

46. This reaction, called oxidation, can kill bacteria, viruses, and odors.

47. When ozone is inhaled, this reaction also damages the respiratory system.

48. In sufficiently large quantities, breathing ozone is fatal for human beings.

49. In smaller quantities, breathing ozone for even a short time can cause adverse health consequences.

50. Breathing ozone can cause epithelial damage, neutrophilic bronchitis, pulmonary edema, and reduced lung function.

51. Breathing ozone can cause cough, wheezing, chest tightness, and shortness of breath.

52. Breathing ozone can compromise the body's ability to fight respiratory infections.

53. Breathing ozone can worsen asthma symptoms.

54. Breathing ozone can worsen symptoms in people with heart disease.

55. Ozone exposure can also irritate the mucous membranes, eyes, and taste buds.

56. Ozone exposure can cause extreme fatigue, somnolence, dizziness, insomnia, and decreased ability to concentrate.

57. While ozone itself causes health problems, it can also react with household

² J.D. McClurkin & D.E. Maier, Half-Life Time of Ozone as a Function of Air Conditions and Movement, Presentation at the 10th Int'l Working Conf. on Stored Product Protection (2010), <http://works.bepress.com/dirk-maier/44/> (finding that ozone's half-life varies based on atmospheric conditions with a maximum half-life of 1,524 minutes (25 hours) in dry still cool air).

substances, such as wood-floor treatments, carpet, paint, and perfume, to form other potentially toxic substances such as formaldehyde.

58. Federal and state authorities agree with the FDA that ozone exposure poses a risk to public health:

- a. The EPA explains that “[w]hen inhaled, ozone can damage the lungs. Relatively low amounts of ozone can cause chest pain, coughing, shortness of breath and, throat irritation. It may also worsen chronic respiratory diseases such as asthma as well as compromise the ability of the body to fight respiratory infections,” and even “[h]ealthy people can experience breathing problems when exposed to ozone.”³
- b. The Consumer Products Safety Commission and EPA explain that “[t]here is no difference, despite some marketers’ claims, between ozone in smog outdoors and ozone produced by these devices Although ozone can be used in reducing odors and pollutants in unoccupied spaces (such as removing smoke odors from homes involved in fires) the levels needed to achieve this are above those generally thought to be safe for humans.”⁴
- c. The New York Department of Health explains that “[a]dults and children who breathe high levels of ozone for a short period of time (minutes or hours) can experience eye, nose and throat irritation, shortness of breath, chest pain and coughing. Breathing high levels of ozone can worsen asthma symptoms. Breathing ozone for a short period of time may worsen symptoms in people with heart disease. Ozone can react with other chemicals in the air to produce additional chemicals and fine particles that can also be irritating to the eyes, nose, throat and lungs.”⁵
- d. The California EPA explains that “[e]xposure to ozone irritates and inflames the lining of the respiratory system Ozone impairs breathing. Elevated exposures to ozone can cause permanent lung damage, and repeated exposure can even increase the risk of dying among persons already in poor health.”⁶
- e. And the California Air Resources Board explains that “[e]xposure to levels of

³ *Ozone Generators that are Sold as Air Cleaners*, EPA, <https://www.epa.gov/indoor-air-quality-iaq/ozone-generators-are-sold-air-cleaners#pubs>.

⁴ CPSC & EPA et al., *Indoor Air Pollution: Introduction for Health Professionals* at 20, EPA (Jan. 1, 2015), https://www.epa.gov/sites/production/files/2015-01/documents/indoor_air_pollution.pdf.

⁵ *Ozone Generators as Indoor Air Cleaners*, N.Y. DEP’T OF HEALTH (Sept. 2008), https://www.health.ny.gov/environmental/indoors/air/docs/ozone_generating_air_cleaners.pdf.

⁶ Cal. Air Resources Bd., *Fact Sheet: Beware of Ozone-Generating Indoor “Air Purifiers,”* CAL. EPA (Mar. 2006), https://ww3.arb.ca.gov/research/indoor/ozone_gen_fact_sheet-a.pdf.

ozone above the current ambient air quality standard can lead to human health effects such as lung inflammation and tissue damage and impaired lung functioning. Ozone exposure is also associated with symptoms such as coughing, chest tightness, shortness of breath, and the worsening of asthma symptoms.”⁷

D. SoClean’s CPAP Sanitizing Process

59. The SoClean devices sanitize CPAP machines by generating ozone and circulating it throughout the user’s CPAP equipment.

60. The SoClean devices work on a variety of different CPAP models and can be used on CPAPs with or without humidifiers.

61. Each SoClean device features an ozone generator, a black hose with a connector, and a chamber. *See* Ex. C (SoClean 2 Photos), Figure 1; Ex. D (SoClean 2 Go Photos), Figure 1.

62. The SoClean 2 has a hard-plastic box as the chamber. *See* Ex. C (SoClean 2 Photos), Figures 1-2.

63. Inside the SoClean 2’s chamber, there is a spot for a filter cartridge. *See* Ex. C (Photos of SoClean 2 Device), Figure 1.

64. The SoClean 2 Go uses a cloth bag with a draw string as the chamber. *See* Ex. D (SoClean 2 Go Photos), Figures 1, 4.

65. On the SoClean 2 Go’s cloth chamber, there is an outside pocket for a filter cartridge. *See* Ex. D (Photos of SoClean 2 Go Device), Figure 4.

66. The approximately 3.5” long and 1” square filter cartridges consist of a plastic shell filled with granulated charcoal.

67. SoClean makes and markets replacement filter cartridges to SoClean owners and represents that the filter must be replaced every six months for the life of the machine.

⁷ Cal. Air Resources Bd., *Ozone and Ambient Air Quality Standards*, CAL. EPA (Oct. 2, 2015), <https://ww3.arb.ca.gov/research/aaqs/caaqs/ozone/ozone.htm>.

68. To set up a SoClean device initially, a user connects the black hose to his CPAP tank's air output opening, where the face-mask hose also attaches. *See* Ex. C (SoClean 2 Photos), Figure 3; *See* Ex. D (SoClean 2 Go Photos), Figure 2.

69. Connecting the black hose sometimes requires an adapter specific to the user's CPAP model.

70. Once connected, the black hose remains attached to the user's CPAP even while the SoClean device is not in use.

71. SoClean recommends that its customers run at least one cleaning cycle every day.

72. During a cleaning cycle, the SoClean device actively generates ozone for approximately 7 to 14 minutes.

73. To run a cleaning cycle, the user places his face mask into the SoClean device's chamber and closes the lid or draw string. *See* Ex. C (SoClean 2 Photos), Figure 2; Ex. D (SoClean 2 Go Photos), Figure 1.

74. The user can then manually initiate a cleaning cycle by pressing a button or series of buttons.

75. Alternatively, the SoClean 2 automatically runs a cleaning cycle every day when its digital clock reads 10:00 AM.

76. When a cleaning cycle starts, the SoClean device begins generating a large quantity of ozone gas that travels through the black hose into the CPAP's tank.

77. From the CPAP's tank, some of the ozone travels to the face mask and accumulates inside the SoClean device's chamber.

78. By design, this process inundates the CPAP mask, hose, and tank with ozone, killing bacteria, viruses, and odors found within.

79. During a cleaning cycle, the SoClean 2 consistently generates 30 ppm of ozone by volume of air circulating through the device. *See* Ex. E (SoClean 2 Lab Reports) at 1.

80. And within a SoClean device's chamber, 140 ppm of ozone accumulates during a cleaning cycle.

81. During and after a cleaning cycle, ozone escapes a SoClean device in two ways.

82. First, ozone is pumped into the user's CPAP machine and, because CPAP machines are not airtight, that ozone vents into the user's bedroom.

83. This occurs because a CPAP machine has an open air path between its air intake (where room air enters the machine to be pressurized) and its air outlet (where the face mask and the SoClean device connect to the machine). *See* Ex. A (Airflow Diagrams), Figure 1.

84. Accordingly, ozone that enters the CPAP's air outlet (where the SoClean and face mask attach) can freely escape through the CPAP's air-intake opening. *See* Ex. A (Airflow Diagrams), Figure 2.

85. Anyone in proximity to the device can then inhale the escaped ozone.

86. SoClean users generally keep their SoClean devices attached to their CPAP machines in the bedroom on a bedside table, as consistently depicted SoClean in marketing materials. *See, e.g.,* Ex. G (SoClean Marketing Materials), Figures 1-2.

87. When a SoClean 2 is run for 12 minutes, 28 ppm of ozone escapes the device and accumulates in a 50-liter Teflon chamber—with or without a filter cartridge installed. *See* Ex. E (SoClean 2 Lab Reports) at 2-3.

88. This is 560 times the FDA's limit on ozone generation and accumulation by medical devices. *See* 21 C.F.R. § 801.415(c)(1).

89. When a SoClean 2 Go is run for 10 minutes, 5.6 ppm of ozone escapes the device

and accumulates in a 27-liter glass chamber—with or without a filter cartridge installed. *See* Ex. F (SoClean 2 Go Lab Report).

90. This is 112 times the FDA’s limit on ozone generation and accumulation by medical devices. *See* 21 C.F.R. § 801.415(c)(1).

91. Second, ozone remains in the CPAP mask, hose, and tank after a cleaning cycle.

92. During normal CPAP use, the user inhales this leftover ozone through the face mask as air from the CPAP machine flows into the mask.

93. SoClean does not advise users of the risk posed by remaining ozone.

94. Buried in the user guides, SoClean advises users to leave the mask in the SoClean device for two hours to “to achieve maximum sanitizing,” SoClean 2 Go User Guide at 12, or so that “all disinfecting is complete,” SoClean 2 User Guide at 16.

95. The SoClean 2 Go User Guide never warns that the two-hour post-cycle waiting period is intended to avoid exposure to unsafe levels of toxic gas. The SoClean 2 User Guide, in an unrelated FAQ on page 18, states: “The activated oxygen disinfects your equipment and naturally breaks down to regular oxygen within two hours.” However, the SoClean 2 User Guide never links the waiting period is intended or required to allow toxic gas to dissipate.

96. But the ozone within the CPAP mask, hose, and tank does not breakdown within two hours.

97. During testing, ozone levels remain at 3 ppm two hours after a SoClean’s cleaning cycle was complete. *See* Ex. E (SoClean 2 Lab Reports) at 4.

98. When using their CPAP after a cleaning cycle, users often complain of a strong odor.

99. The odor is attributable to ozone gas that remains in the CPAP mask, hose, and

tank.

E. SoClean’s False and Misleading Representations

100. SoClean has made material misrepresentations about the SoClean devices’ ozone output, which are not only false but dangerous for consumers, throughout its television, online, radio, text messaging, and print advertising campaigns.

1. SoClean’s Failure to Disclose Its Ozone Generation and Use of the Term “Activated Oxygen”

101. The SoClean devices’ packaging does not disclose that the SoClean devices generate ozone or the levels of ozone generated.

102. Marketing materials for the SoClean devices do not disclose that they generate ozone or the levels of ozone generated.

103. Instead, SoClean represents to consumers that it uses “activated oxygen” to sanitize CPAP machines.

104. These omissions and representations are false and misleading.

105. In reality, the SoClean devices use ozone to sanitize CPAP machines.

106. As the EPA explains: “Manufacturers and vendors of ozone devices often use misleading terms to describe ozone,” similar to activated oxygen, that “suggest that ozone is a healthy kind of oxygen.”⁸

107. However, “[o]zone is a toxic gas with vastly different chemical and toxicological properties from oxygen.” *Id.*

108. SoClean has represented across many forums that the SoClean devices use “activated oxygen” while failing to disclose that the devices use ozone. For example:

a. The product packaging for the SoClean 2 never mentions ozone and the box

⁸ *Ozone Generators that are Sold as Air Cleaners*, EPA (Nov. 27, 2018), <https://www.epa.gov/indoor-air-quality-iaq/ozone-generators-are-sold-air-cleaners#pubs>.

states: “Activated Oxygen powers through your CPAP reservoir, hose, and mask.” *See* Ex. H (SoClean 2 Packaging), Figure 6.

- b. SoClean’s website homepage does not mention ozone and but states: “SoClean’s activated oxygen cleaning completely sanitizes your CPAP mask, hose, and reservoir without any water or chemicals.”⁹
- c. Since at least 2015, SoClean has used a promotional brochure advertising the SoClean devices that does not mention ozone and states: “SoClean’s activated oxygen completely sanitizes your mask, hose, and reservoir without any water or chemicals.”
- d. SoClean’s Amazon Store page for the SoClean devices states: “The SoClean CPAP Cleaner and Sanitizer uses activated oxygen to eliminate any germs and bacteria that may be lingering in your CPAP equipment. SHOP NOW.”¹⁰
- e. The SoClean 2 Amazon product page maintained by the company fails to disclose that the SoClean 2 generates ozone and states: “The SoClean CPAP sanitizing machine uses safe, natural, activated oxygen to thoroughly sanitize and disinfect your entire CPAP system.”¹¹
- f. On the SoClean Website, in answer to the FAQ “Why do I smell ozone in my mask at night when the unit ran in the morning?” SoClean falsely states: “What you smell is not ozone; the equipment is being oxidized with activated oxygen, and that is what you smell – it is completely safe. Some suggestions to lessen the smell: 1) Make sure you use the neutralizing pre-wash. 2) Increase the cleaning time to 12 minutes for a few weeks, then decrease to 7 minutes. 3) Blow air from your CPAP through your mask for 5 minutes before using it. 4) Do not use fragrance wipes or any fragrance products to clean you CPAP equipment, as this will intensify the smell.”¹²
- g. The 2014 and 2017 online versions of the SoClean 2 User Guide never mentions ozone and state that SoClean disinfects with “activated oxygen.”¹³
- h. The online version of the SoClean 2 Go User Guide never mentions ozone and states: “The SoClean 2 Go uses no fluids in its operation. It sanitizes with

⁹ SOCLEAN, www.SoClean.com (last visited Apr. 10, 2019).

¹⁰ *SoClean: SoClean Devices*, AMAZON, <https://www.amazon.com/stores/page/D8D76027-78E7-4B7F-A322-5AB89F68D8DD> (last visited Apr. 20, 2019). Amazon Store content is created by the brand itself. *See Stores*, AMAZON, <https://advertising.amazon.com/products/stores> (last visited Apr. 20, 2019).

¹¹ *SoClean 2 + Respiromics DreamStation and System One Adapter*, AMAZON, <https://www.amazon.com/dp/B00JWVV4VW> (last visited Apr. 20, 2019).

¹² *SoClean and Activated Oxygen FAQs*, SOCLEAN, <https://www.soclean.com/sleep-talk/documentation/soclean-activated-oxygen-faqs/> (last visited Apr. 25, 2019).

¹³ *2017 SoClean 2 User Guide*, SOCLEAN, https://www.soclean.com/wp-content/uploads/2017/03/soclean2_manual_RevH.pdf.

activated oxygen. No fluids or water are used in this process.”¹⁴

109. Buried deep within SoClean’s website are blog posts, user-support FAQs and a “white paper” admitting that “activated oxygen” is, in actuality, ozone.

110. These webpages often suggest that SoClean uses a safe form of ozone:

a. The Brochure states: “The SoClean uses ozone – also known as O₃ or activated oxygen – to sanitize CPAP equipment. Ozone is a 100% safe, naturally occurring gas that has been used to purify water since the 1800s. In today’s world, it’s a trusted sanitizing process used by hospitals, food handlers and the hotel industry.”

b. An FAQ titled “What Is Activated Oxygen” states:

Activated oxygen also known as ozone, or O₃ is defined by Merriam-Webster dictionary as: 1. a form of oxygen that is found in a layer high in the earth’s atmosphere. 2. fresh healthy air especially near the sea. Activated oxygen is a three atom oxygen molecule.

This three atom molecule is a colorless gas with powerful oxidizing properties, formed from oxygen by electrical discharges or ultraviolet light. It differs from normal oxygen (O₂) but over time or with forced filtration, will break back down to normal oxygen (O₂) that we breathe.

Many become confused over the term ozone. There is good ozone and there is bad ozone. Most commonly used is bad ozone which is linked to high ozone alerts or smog alerts in certain areas of the world. This kind of ozone is mixed with toxic gases that can be breathed in. Good ozone is found in our upper atmosphere or you may smell the essence of ozone after a thunderstorm. Activated oxygen (ozone) is known as one of the best and most effective means to natural disinfection. This process is commonly used in array of applications such as public water filtration, fruit and vegetable handling, hotel housekeeping, and hospital disinfection. Please see common FAQs to learn more about activated oxygen (ozone) or see activated oxygen in SoClean to learn how the SoClean safely disinfects your CPAP equipment.”¹⁵

111. Not only are the foregoing obscure and difficult to locate, but they are themselves affirmatively false and misleading.

¹⁴ *SoClean 2 Go User Guide*, SOCLEAN, https://www.soclean.com/wp-content/uploads/2014/10/soclean2Go_manual_revA.pdf.

¹⁵ *What is activated oxygen?*, SOCLEAN, <https://www.soclean.com/sleep-talk/documentation/activated-oxygen/> (last visited Apr. 25, 2019).

2. Representations that the SoClean Devices Use No “Chemicals” and/or “Harsh Chemicals”

112. SoClean falsely represents that its devices use no “chemicals” or “harsh chemicals” to clean CPAP machines.

113. These representations are false and misleading.

114. The SoClean devices use ozone gas to clean CPAP machines.

115. Ozone is a chemical.

116. Ozone is a harsh chemical.

117. SoClean itself has compared ozone’s dangers to those of chlorine bleach. *See* Ex. I (Jan. 24, 2013 Blog Post) at 1.

118. SoClean has repeatedly represented that its devices use no “chemicals” or “harsh chemicals” to clean CPAP machines across many forums. For example:

- a. The box for the SoClean 2 states represents that the device uses “No water or chemicals.” Ex. H (SoClean 2 Packaging), Figure 3.
- b. Since at least March 28, 2016, SoClean’s website homepage has read: “SoClean kills 99.9% of CPAP germs and bacteria in your mask, hose and reservoir with no disassembly, no water, and no chemicals in order to enhance your home CPAP experience.”¹⁶
- c. SoClean has aired the television commercial “Getting Sick from a Dirty CPAP” at least 10,929 times nationwide since 2018, representing that the SoClean devices use “no harsh chemicals” to clean CPAP machines.
- d. SoClean has aired the television commercial “CPAP Cleaner and Sanitizer” at least 22,058 times nationwide since 2016, representing that the SoClean devices use “no chemicals” to clean CPAP machines.
- e. SoClean has aired the television commercial “Safely Sanitize and Disinfect” at least 6,325 times nationwide between 2017 and July 2018, representing that the SoClean devices use “no harsh chemicals” to clean CPAP machines.
- f. SoClean has aired the television commercial “Automated CPAP Sanitizer” at least 512 times nationwide in 2018, representing that the SoClean devices use

¹⁶ SOCLEAN, www.SoClean.com (last visited Apr. 10, 2019).

“no harsh chemicals” to clean CPAP machines.

3. Representations that the SoClean Devices Are “Safe” and “Healthy” for Use

119. SoClean often markets its devices as “safe” and “healthy” while failing to disclose their use of ozone.

120. These representations are false and misleading.

121. A device that releases toxic gas into a user’s bedroom at levels exceeding federal regulations is not “safe” or “healthy.”

122. SoClean has repeatedly represented that its devices are safe and healthy across many forums while failing to disclose their use of ozone. For example:

- a. The packaging for the SoClean 2 states: “Breathe Healthy, Breathe SoClean.” *See* Ex. H (SoClean 2 Packaging), Figure 4.
- b. Since at least March 28, 2016, SoClean’s website homepage has represented that the SoClean devices offer “Safer, healthier CPAP cleaning.”¹⁷
- c. A brochure advertising the SoClean and SoClean 2 Go used since at least 2015 reads: “The SoClean makes it easy for any CPAP user to safely and naturally clean and sanitize their equipment on a daily basis.”
- d. A brochure advertising the SoClean and SoClean 2 Go used since at least 2015 reads: “Featuring the same safe, effective sanitizing process as the SoClean, the SoClean 2 Go is the perfect travel companion for any CPAP user – so small it can fit easily anywhere.”
- e. SoClean has aired the television commercial “Getting Sick from a Dirty CPAP” at least 10,929 times nationwide since 2018, representing that the SoClean devices help users stay healthy.
- f. SoClean has aired the television commercial “CPAP Cleaner and Sanitizer” at least 22,058 times nationwide since 2016, representing that the SoClean devices improve users’ health.
- g. SoClean has aired the television commercial “Safely Sanitize and Disinfect” at least 6,325 times nationwide between 2017 and July 2018, representing that the SoClean devices safely sanitize CPAP masks and hoses.

¹⁷ SOCLEAN, www.SoClean.com (last visited Apr. 17, 2019).

- h. In a brochure that consumers can obtain from SoClean only if they provide a name and valid email address, SoClean states that: “The SoClean uses ozone – also known as O₃ or activated oxygen – to sanitize CPAP equipment. Ozone is a 100% safe, naturally occurring gas that has been used to purify water since the 1800s. In today’s world, it’s a trusted sanitizing process used by hospitals, food handlers and the hotel industry.”
- i. An Amazon product page maintained by the company reads: “The SoClean CPAP sanitizing machine uses safe, natural, activated oxygen to thoroughly sanitize and disinfect your entire CPAP system.”¹⁸
- j. A SoClean FAQ page represents that: “What is the concentration of ozone inside the SoClean CPAP cleaner and sanitizer? SoClean uses enough ozone to thoroughly sanitize your CPAP equipment and by the time you open the chamber it will have decreased to 0 ppm.”¹⁹

4. Representations that the SoClean Devices Use the Same Sanitizing Process Found in Hospitals

123. SoClean represents that its devices use the same sanitizing process found in hospitals.

124. This representation is false and misleading.

125. Hospital ozone decontamination systems can only be used in vacant, sealed rooms.

126. Hospitals cannot and do not use ozone sanitizers in spaces occupied by patients.

127. SoClean devices, however, are sold for use in the home, specifically bedrooms, and marketing materials often depict the SoClean device on the user’s nightstand.

128. SoClean has repeatedly represented that its devices use the same sanitizing process found in hospitals. For example:

- a. Since at least 2015, SoClean has used a promotional brochure advertising the SoClean devices that includes:

¹⁸ *SoClean 2 + Respironics DreamStation and System One Adapter*, AMAZON, <https://www.amazon.com/dp/B00FKBU0X6> (last visited Apr. 15, 2019).

¹⁹ *SoClean and Activated Oxygen FAQs*, SOCLEAN, <https://www.soclean.com/sleep-talk/documentation/soclean-activated-oxygen-faqs/> (last visited Apr. 25, 2019).

Did you know that SoClean uses the same sanitizing process found in:



- b. Since at least 2015, SoClean has used a “rack card” advertising the SoClean devices that includes:

SoClean uses the same sanitizing process found in:



www.SoClean.com

- c. The box for the SoClean 2 features a similar image that states: “SoClean uses the same sanitizing process found in:” “water,” “produce,” “hotels,” and “hospitals.” See Ex. H (SoClean 2 Packaging), Figure 5.
- d. The SoClean 2 Amazon product page maintained by the company reads “Activated oxygen[.] SoClean uses the same safe and proven sanitizing and disinfecting process found in water purification, produce handling, hotel housekeeping and hospital sanitizing.”²⁰
- e. In a brochure that SoClean requires consumers to provide a name and valid email address to obtain, SoClean states that: “The SoClean uses ozone – also known as O₃ or activated oxygen – to sanitize CPAP equipment. Ozone is a 100% safe, naturally occurring gas that has been used to purify water since the 1800s. In today’s world, it’s a trusted sanitizing process used by hospitals, food handlers and the hotel industry.”

129. In context, SoClean’s other representations regarding “water purification,” “produce handling,” and “hotel housekeeping” add to the misleading nature of its representation

²⁰ *SoClean 2 + Respironics DreamStation and System One Adapter (SoClean 2 CPAP Cleaner and Sanitizer Bundle with Free Adapter)* by SoClean, AMAZON, <https://www.amazon.com/dp/B00FKBU0X6> (last visited Apr. 21, 2019).

regarding “hospital sanitizing.”

130. Read together, they suggest that ozone is a benign substance suitable for human consumption and use in occupied spaces.

131. However, ozone sanitizing for water purification and produce handling are industrial applications of ozone sanitizing, not household uses. These applications are subject to extensive safety procedures to avoid human ozone exposure. All ozone dissipates before humans may consume the water or produce treated with ozone.

132. With regard to hotel housekeeping, some U.S. hotels used ozone air purifiers to remove odors from unoccupied hotel rooms in the 1990s. However, the technology could never be used in occupied hotel rooms.

5. Representations that the Charcoal Filter Cartridges Convert “Activated Oxygen” into “Normal Oxygen”

133. SoClean represents that the filter cartridges convert “activated oxygen” back into “normal oxygen.”

134. This representation is false and misleading.

135. The FDA has determined that there is no reliable way to guarantee the rapid breakdown of ozone to prevent its accumulation in enclosed spaces. *See* FDA Final Ozone Rulemaking, 39 Fed. Reg. 13773, ¶ 6 (Apr. 17, 1974).

136. The filter does not prevent the SoClean devices from emitting ozone into the environment.

137. The SoClean filter does not prevent ozone from escaping into the atmosphere.

138. The SoClean filter has no measurable effect on ozone accumulation.

139. SoClean has repeatedly represented across many forums that its filters convert “activated oxygen” into “regular oxygen.” For example:

- a. The SoClean webpage selling replacement filters states that “[t]he Cartridge Filter converts activated oxygen back to regular oxygen as it leaves the SoClean 2 chamber.”²¹
- b. The 2017 online version of the SoClean 2 User Guide states: “Additionally, any excess activated oxygen passes through a filter which converts it back to regular oxygen before release.”²²
- c. The online version of the SoClean 2 Go User Guide states: “This filter converts activated oxygen back into normal oxygen. Replace every 6 months.”²³
- d. A SoClean FAQ page represents that: “What is the concentration of ozone inside the SoClean CPAP cleaner and sanitizer? SoClean uses enough ozone to thoroughly sanitize your CPAP equipment and by the time you open the chamber it will have decreased to 0 ppm.”²⁴

6. Representations that SoClean Is a Sealed System, a Closed-Loop System, or that No “Activated Oxygen” or Ozone Escapes the Devices

140. SoClean represents that the SoClean is a “closed system” and that no “activated oxygen” escapes the device.

141. This representation is false and misleading.

142. A closed-loop system is one in which ozone circulates within but does not leave the device.

143. The SoClean devices circulate ozone through the CPAP machine which is then released into the ambient air or breathed by the CPAP user.

144. SoClean has repeatedly represented across many forums that its devices are a “closed system” and/or that no “activated oxygen” escapes. For example:

- a. A “CPAP cleaning demo video” hosted on the SoClean homepage shows

²¹ *Cartridge Filter Kit – SoClean 2*, SOCLEAN, <https://www.soclean.com/product/cartridge-filter-kit-soclean-2/> (last visited Apr. 15, 2019).

²² *2017 SoClean 2 User Guide*, SOCLEAN, https://www.soclean.com/wp-content/uploads/2017/03/soclean2_manual_RevH.pdf.

²³ *2014 SoClean 2 User Guide*, SoClean, https://www.soclean.com/wp-content/uploads/2014/04/soclean2_manual_RevE.pdf.

“activated oxygen” circulating through the CPAP machine and SoClean device, but no “activated oxygen” escaping the CPAP machine during the cleaning process.²⁵ See Ex. G (Marketing Materials), Figure 3. Online, the video appears next to a “Buy Now” button.

- b. A SoClean FAQ webpage represents the following: “What is the concentration of ozone inside the SoClean CPAP cleaner and sanitizer? SoClean uses enough ozone to thoroughly sanitize your CPAP equipment and by the time you open the chamber it will have decreased to 0 ppm.”²⁶
- c. The 2017 online version of the SoClean 2 User Guide states: “The SoClean produces activated oxygen in a closed system.”²⁷
- d. The 2014 online version of the SoClean 2 User Guide states: “Is the SoClean harmful to me or the environment? No. The activated oxygen generator is always kept at a safe level and never reaches the outside environment.”²⁸

145. SoClean has made additional false and misleading representations about the SoClean devices similar to those alleged in paragraphs 100 to 144.

146. Upon information and belief, SoClean perpetuates the falsehoods alleged in paragraphs 100 to 145 by paying or otherwise incentivizing individuals to create blog posts and online reviews repeating the falsehoods.

147. Upon information and belief, SoClean perpetuates the falsehoods alleged in paragraphs 100 to 145 by using search engine optimization services.

148. SoClean has made the misrepresentations outlined in paragraphs 100 to 145 since at least January 2012 and they continue today.

F. The Effects of SoClean’s False Advertising on Consumers

149. The foregoing false claims deceive consumers into believing that the SoClean

²⁵ SOCLEAN, <https://www.soclean.com> (last visited Apr. 21, 2019).

²⁶ *SoClean and Activated Oxygen FAQs*, SOCLEAN, <https://www.soclean.com/sleep-talk/documentation/soclean-activated-oxygen-faqs/> (last visited Apr. 16, 2019).

²⁷ *2017 SoClean 2 User Guide*, SOCLEAN, https://www.soclean.com/wp-content/uploads/2017/03/soclean2_manual_RevH.pdf.

²⁸ *2014 SoClean 2 User Guide*, SOCLEAN, https://www.soclean.com/wp-content/uploads/2014/04/soclean2_manual_RevE.pdf.

devices do not generate ozone, do not release ozone into the atmosphere, and are safe, healthy, and suitable for use in consumer's bedrooms.

150. Due to the nature of SoClean's business, its customers all have breathing problems for which they are receiving medical treatment in the form of CPAP therapy. In fact, CPAP users are so concerned about their health that they experience the considerable inconvenience of using a CPAP machine and wearing a CPAP face mask to sleep every night.

151. Because of this, CPAP users would find the risk posed by the SoClean devices generating unsafe levels of toxic gas, which is then pumped into their CPAP machines and their bedrooms, material to their purchasing decisions.

152. Consumers have returned their SoClean devices after learning that the devices emit ozone gas and about the dangers of ozone.

153. SoClean's false representations regarding its use of ozone and its devices' safety have harmed consumers and pose a threat to public health.

154. Ozone exposure at levels exceeding .05 ppm negatively affects human health.

155. Epidemiologic studies suggest that those with existing breathing problems may experience adverse effects from ozone exposure at concentrations even lower than .05 ppm.

156. The FDA's MAUDE database, where consumers can report adverse experiences with medical devices, contains the following consumer complaints about SoClean, which are attributable to the adverse effects of unwitting ozone exposure:

- a. "I purchased a soclean c-pap-cleaner. I followed all of the directions i.E., preashed the unit, hoses etc. I then cleaned the cpap machine using soclean at the recommended settings. That evening i slept with the cleaned machine. The smell of ozone was strong. The mfr calls ozone activated oxygen. After about 6 hours, i experienced a severe asthma attack which i have never had before. Treatment with rescue inhaler, steroids, bronchodilators. I have cough

predominant asthma. The coughing was so severe that i injured my back.”²⁹

- b. “Purchased a soclean 2 cpap sanitizer from apria direct health care. Upon using machine a strong odor was noted on mask, but was told this was normal and that it was like the ocean smell. After the first week i began having trouble with my breathing. It continued to get worse. Started breathing treatments and prednisone did not help. I then found out that they used ozone to sanitize the cpap machine. Checked the (b)(6) clinic web site only to find ozone is an irritant and can cause asthma attacks. Called apira direct and they told me to return the machine. They do not advise you of this danger. I ended up in an urgent care center today for the asthma attack.”³⁰
- c. “After approximately 3 months of using soclean 2 cpap cleaner i noticed i was getting sick, started having chest pains for short periods of time each day and felt tired all the time. After research of the product, found it uses ozone to disinfect and found i had most of the symptoms of excess ozone in my system. After 3 days of not using it i am feeling much better with no instances of chest pain and my cold is going away along with my lungs clearing up. I will be seeing my doctor in 2 weeks to be referred to a cardiologist for assessment.”³¹
- d. “I used the soclean cpap cleaning machine, after i purchased it for (b)(6). It used ozone to cleanse cpap machine. There was ozone residue left in my cpap after using the soclean, and that ozone residue burned my sinuses and lungs. This product is hazardous to people’s respiratory systems and it causes pain. It caused me severe pain. This product is unregulated and it should be regulated. I went to the doctor and was told to discontinue use of the soclean machine.”³²
- e. “I purchased a soclean2 pap disinfecting device on (b)(6) 2018, from (b)(6) center in (b)(6), to clean my cpap unit. Since using the product from that time, i have noticed my sense of taste and smell have diminished dramatically as well as a very dry and an unusual taste in my mouth. Everything i eat tastes bland. Can you tell me if this product has side effects that are causing me these issues? i have not changed anything else in my diet. Including no new medications. Is there residue left from the cleaning that are irritating my mucous membranes? i have appointments to see a pulmonary and nose/throat specialist as well as my dentist to rule out any other medical issues. As i mentioned before, there have been no changes to my diet or lifestyle and current blood tests show no

²⁹ MAUDE Adverse Event Report: Inceptus SoClean 2, FDA (Sept. 20, 2016), https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfmaude/detail.cfm?mdrfoi_id=5969746&pc=LRJ.

³⁰ MAUDE Adverse Event Report: SoClean2, FDA (Apr. 27, 2018), https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/detail.cfm?mdrfoi_id=7472673&pc=LRJ.

³¹ MAUDE Adverse Event Report: SoClean Inc., FDA (Mar. 15, 2018), https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/detail.cfm?mdrfoi_id=7352173&pc=LRJ.

³² MAUDE Adverse Event Report: SoClean Inc., FDA (Aug. 18, 2018), https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfmaude/detail.cfm?mdrfoi_id=7805317&pc=LRJ.

issues.”³³

- f. “Caller says that the product is used to clean his cpap machine. Caller says that on the side of this nose he gets rough and irritated skin that is painful after using the product. The irritation goes away when he does not use the machine and reappears anytime he uses it. Caller is concerned that the device is damaging his lungs.”³⁴
- g. “Purchased ‘soclean’ for use with cpap. Had a small cut on nose. When using the ‘soclean’ to sanitize my cpap, i developed oozing sores on my nose, similar to cold sores. When i traveled for a week and continued to use the cpap but not the ‘soclean’, the sores cleared up. Returned home and used ‘soclean’ and the sores returned. Was on vacation for 2 weeks and the sores cleared up. I returned home and started using the ‘so clean’ and they returned. I can only conclude that it is the ‘soclean’ because i continue to use the cpap when i travel but not the soclean and the sores clear up.”³⁵
- h. “Reporter stated that he uses the soclean cpap cleaner and sanitizer machine and each time he used this machine it produced a gunk like type of substance that gives him headache, bloody nose and respiratory problems. He further reported that each time he sterilizes the machine it goes away for a while and the gunk like substance comes back.”³⁶
- i. “I have been a cpap user for over 10 years. Approx a year ago, i purchased a cpap sanitizer from soclean. It uses ozone to clean the equipment. I don't smoke or drink. I was diagnosed with larynx cancer about six months ago and had radiation treatment at (b)(6). My dr, dr (b)(6) thought it was unusual to develop larynx cancer without smoking or drinking. I did some research and found that ozone can cause cancer. I can only tell there was an ozone smell in the equipments hours after i used the unit. In fact the bedroom smelled of it too. It is my belief, that this unit’s ozone output caused my cancer.”³⁷

157. These experiences are representative of consumers’ experiences with unwitting ozone exposure through the SoClean devices and similar consumer complaints can be found across

³³ MAUDE Adverse Event Report: SoClean, Inc FDA (Feb. 27, 2019), https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/detail.cfm?mdrfoi_id=8377760&pc=LRJ.

³⁴ MAUDE Adverse Event Report: SoClean Inc., FDA (Apr. 8, 2019), https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/detail.cfm?mdrfoi_id=8496305&pc=LRJ

³⁵ MAUDE Adverse Event Report: SoClean Inc., FDA (Apr. 25, 2019), https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/detail.cfm?mdrfoi_id=8555625&pc=LRJ.

³⁶ MAUDE Adverse Event Report: SoClean, Inc, FDA (May 13, 2019), https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/detail.cfm?mdrfoi_id=8608478&pc=LRJ.

³⁷ MAUDE Adverse Event Report: SoClean, Inc., FDA (July 1, 2019), https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/detail.cfm?mdrfoi_id=8758398&pc=LRJ.

the internet.

G. The Effects of SoClean’s False Advertising on 3B

158. 3B and SoClean are direct competitors in the market for automatic CPAP-equipment sanitizing devices intended for daily or regular use.

159. SoClean commands at least a ninety-percent market share.

160. 3B commands approximately five percent of the market.

161. Three other competitors, all SoClean knockoffs, collectively control the remaining five percent of the market—Sleep8, VirtuClean, and Respify.

162. Sleep8, VirtuClean, and Respify all use ozone.

163. The Lumin is the only device in the market that does not operate using ozone gas.

164. Consumers seeking an alternative to ozone sanitizers have no options in the market other than the Lumin devices.

165. 3B actively advertises the Lumin as an alternative to ozone sanitizers, such as the SoClean.

166. However, 3B’s advertising is overshadowed by SoClean’s prolific false advertising, on which it has spent over \$100,000,000.

167. Although most consumers are deceived by SoClean’s false advertising, a small minority manage to uncover SoClean’s use of ozone gas.

168. Those consumers often purchase the Lumin because of concerns over ozone.

169. Online reviews for the Lumin reflect this fact, for example:

- a. “Recently, my son had pneumonia from not cleaning his C-PAP frequently enough! So I bought this Lumin! Less costly as the ‘other cleaner’ and uses UV light instead of ozone. I had read many negative things about using ozone

to ‘sterilize’ the C-PAP, so I thought I would give this one a try.”³⁸

- b. “The [Lumin] machine works by UVC light. There are other systems that use ozone but I did alot of reading, and ozone is pretty dangerous and causes lung irritation. It should not be used in a home period, or I definitely would not use near anyone with a breathing issue, children or pets. So ultraviolet disinfection made more sense to me.”³⁹
- c. “Like that there i[s] no harmful OZONE in [the Lumin]!”⁴⁰
- d. “I owned a So Clean cleaner and because of the ozone I developed a rash around my nose and chin that would itch. I contacted So Clean and they told me to use wipes and I did but the problem persisted. I also read that the ozone itself was very bad for respiratory conditions such as COPD of which I have. Do the research. I would no [sic] recommend the So Clean device for these reasons. I decided to try Lumin. No Ozone.”⁴¹
- e. “[The Lumin uses n]o ozone which I have researched is bad for you.”⁴²
- f. “I’m a review and research nut! So before buying a unit for my Sig/other I researched the pros and cons and a scientific level. I didn’t like the Ozone health risks involved in the other popular models.”⁴³
- g. “I absolutely refuse to use a machine that generates ozone, as most of these types of machines do. This unit, however, uses UV light and I have to tell you: it really does work.”⁴⁴
- h. “Other models use Ozone to clean CPAP mask and hose, ozone is an irritant to mucus membranes.”⁴⁵

³⁸ Donna Kane, *Lumin Customer Review: Love It!*, AMAZON (July 16, 2019), <https://web.archive.org/save/https://www.amazon.com/gp/customer-reviews/R2U1TPOFYITOFQ>

³⁹ LizV, *Lumin Review: Useful for More than CPAP*, WALMART (Nov. 11, 2018), <https://www.walmart.com/reviews/product/395359101>.

⁴⁰ Bttrfly, *Lumin Review: No Ozone Damage to Lungs Here!*, WALMART (Aug. 5, 2019), <https://www.walmart.com/reviews/product/395359101>.

⁴¹ Tom Burke, Comment to *Lumin CPAP UV Cleaner Review*, SLEEP RESTFULLY (Mar. 18, 2019, 11:42 AM), <https://www.sleeprestfully.com/blog/lumin-cpap-cleaner-review/>.

⁴² reen5horse, *3B Lumin CPAP Cleaner Review: Amazing Unit*, AMAZON (Oct. 19, 2018), https://www.amazon.com/review/R3K8FQL3AIETRN/ref=cm_cr_srp_d_rdp_perm?ie=UTF8.

⁴³ Sandra P., *3B Lumin CPAP Cleaner Review: Best Way to Sanitize CPAP and Everything Else*, AMAZON (June 24, 2019), www.amazon.com/review/R3S13F0CQ7DOYW.

⁴⁴ Jeffrey Wickersty, *3B Lumin CPAP Cleaner Review: Was Skeptical, But It Really Does Work*, AMAZON (May 13, 2019), <https://www.amazon.com/gp/customer-reviews/R1CTG2VMUM113Z>.

⁴⁵ Shirley, *3B Lumin CPAP Cleaner Review: No Extra Cleaning Agents to Purchase Monthly*, AMAZON (Aug. 5, 2019), <https://www.amazon.com/gp/customer-reviews/R8JWO4AH41MD4>.

- i. “I’ve just become a CPAP user and having looked into all types of cleaners, I chose this one. I chose [the Lumin] because it is quick, easy to use, and doesn’t use ozone which I gather can have ill effects. I love it and would thoroughly recommend it.”⁴⁶
- j. “My wife was going to get one of those ozone-based cleaners but, after reading about the pros and cons of ozone, I made a pre-emptive purchase and got her [the Lumin].”⁴⁷
- k. “I bought [the Lumin] because I have two different masks and didn’t really want to go with the ozone cleaner.”⁴⁸
- l. “Highly recommended No Ozone problems like other systems”⁴⁹
- m. “Does not emit ozone like other CPAP cleaners do and is versatile for sanitizing other items.”⁵⁰

170. In absence of SoClean’s false advertising, more consumers would investigate alternatives to ozone-sanitizers and discover the Lumin.

171. In absence of SoClean’s false advertising, more consumers would purchase the Lumin.

172. Based on the foregoing, SoClean’s false advertising causes consumers to purchase SoClean’s products when they would otherwise purchase 3B’s products.

H. SoClean’s Deception Is Intentional

173. SoClean’s conduct shows that the company intentionally deceives consumers.

174. SoClean knows that consumers harbor concerns over ozone gas. For example, in a

⁴⁶ Barbara S. Robertson, *3B Lumin CPAP Cleaner Review: CPAP Cleaner*, AMAZON (July 28, 2019), <https://www.amazon.com/gp/customer-reviews/R36DBSL718CURS>.

⁴⁷ Duane B., *3B Lumin CPAP Cleaner Review: Does a Good Job*, AMAZON (Dec. 30, 2018), <https://www.amazon.com/gp/customer-reviews/R165PWRLVH3IUB>.

⁴⁸ Anna, *3B Lumin CPAP Cleaner Review: Affordable*, AMAZON (Nov. 21, 2018), <https://www.amazon.com/gp/customer-reviews/RL62MH702CG9Q>.

⁴⁹ Mona K., *3B Lumin CPAP Cleaner Review: Highly Recommended No Ozone Problems Like Other Systems*, AMAZON (July 5, 2018), <https://www.amazon.com/gp/customer-reviews/R1TZML3XH14QWL>.

⁵⁰ Brap, *3B Lumin CPAP Cleaner Review: Easy to Use*, AMAZON (Mar. 26, 2019), <https://www.amazon.com/gp/customer-reviews/R3MXWN78XS28UT>.

2013 blog post, SoClean stated that “[t]he average person equates the word ‘ozone’ with smog.” *See* Ex. I (Jan. 24, 2013 Blog Post).

175. SoClean has made representations that contradict the falsehoods outlined in Section E, which suggests it knows the truth but intentionally misrepresents it. For example, in a 2013 blog post SoClean compared ozone to chlorine bleach, which “is incredibly powerful and can be dangerous-even lethal.” Ex. I (Jan. 24, 2013 Blog Post).

176. And the false representations outlined in Section E artfully skirt the truth about ozone, suggesting that SoClean knows the truth but intentionally misrepresents it. For example, SoClean’s representations that it uses the same process employed in “water purification,” “produce handling,” “hotel housekeeping” and “hospital sanitizing” show that SoClean is familiar with commercial or industrial uses of ozone gas that require extensive safety precautions. However, SoClean lists those applications in a way that suggests ozone is a benign substance suitable for human consumption and use in occupied spaces, which it is not.

177. If SoClean did not intend to deceive consumers, it would provide consumers with reasonable warnings about the risk of ozone exposure and suggested precautions. For example, SoClean would advise consumers of the minimum room size in which the SoClean devices should be used to avoid unsafe ozone accumulation, as required by the FDA regulations. However, SoClean provides no such warnings, which would enable consumers to protect their own health while using the SoClean devices.

178. SoClean clearly believes that consumers would not purchase its devices if they knew about its use of ozone and ozone’s detrimental effects. For example, when 3B publicized these facts, SoClean retaliated by initiating an NAD proceeding to silence 3B.

179. SoClean intentionally misrepresents its products because it knows that consumers

would be highly concerned about its devices' use of ozone and the corresponding dangers, which would impact consumer purchasing decisions.

CLAIMS

COUNT ONE

False Advertising – Lanham Act, 15 U.S.C. § 1125(a)

180. 3B repeats and realleges all the preceding paragraphs of this Complaint as if fully set forth herein.

181. SoClean made false and misleading statements concerning its products and/or services.

182. The deception was material in that it was likely to influence purchasing decisions.

183. SoClean competes directly with 3B's CPAP sanitizing device in the relevant market, and SoClean's false and misleading statements actually deceived or had a tendency to deceive a substantial portion of the intended audience.

184. SoClean knew that the above described advertising claims are false and/or misleading and are likely to deceive the public.

185. As a direct and proximate result of SoClean's wrongful conduct, 3B was injured, and was likely to be injured, in terms of declining sales, lost profits, loss of goodwill, and other injuries.

186. As a direct and proximate result of its wrongful conduct, SoClean has realized profits and other benefits to which it is not entitled.

187. SoClean's acts constitute a violation of the Lanham Act and entitle 3B to recover SoClean's profits, 3B's damages, and the costs of this action pursuant to 15 U.S.C. § 1117(a).

188. Because of the circumstances of the case and SoClean's egregious conduct, 3B is entitled to have its recovery upwardly adjusted pursuant to 15 U.S.C. § 1117(a).

189. Because SoClean acted intentionally, willfully, and/or in bad faith, this an exceptional case entitling 3B to recover its reasonable attorneys' fees pursuant to 15 U.S.C. § 1117(a).

COUNT TWO
Unfair Competition – New York Common Law

190. 3B repeats and realleges the allegations set forth in Count One and paragraphs 1-149 of this Complaint, as if fully set forth herein.

191. SoClean's acts and omissions as described herein constitute unfair competition against 3B.

192. SoClean's unfair competition has harmed and is continuing to harm 3B, its business, and its goodwill.

193. In addition to monetary harm, 3B has suffered and is continuing to suffer irreparable harm as a result of SoClean's unfair competition.

COUNT THREE
Deceptive Acts and Practices, N.Y. Gen. Bus. Law § 349

194. 3B repeats and realleges the allegations set forth in paragraphs 1-149 of this Complaint as if fully set forth herein.

195. SoClean's acts and practices were deceptive and misleading in a material way.

196. SoClean set out to intentionally mislead consumers and the general public, including consumers and the public at large in New York.

197. SoClean's deceptive acts or practices threaten the public health.

198. As a direct and proximate result of SoClean's wrongful acts, 3B has been injured and incurred damages in an amount to be proven at trial.

199. SoClean acted willfully and in bad faith. Accordingly, the damages sustained by 3B as a result of the unlawful conduct alleged herein should be trebled in accordance with N.Y. Gen. Bus. Law § 349(h).

COUNT FOUR
False Advertising, N.Y. Gen. Bus. Law § 350

200. 3B repeats and realleges the allegations set forth in paragraphs 1-149 of this Complaint as if fully set forth herein.

201. SoClean's false and deceptive advertising contains materially misleading statements of fact that concern the performance of the product.

202. These advertisements were aimed at the consumer public at large.

203. SoClean's marketing has caused and is likely to cause confusion and mistake and has deceived and is likely to deceive potential customers and the general purchasing public.

204. SoClean's false and misleading statements of fact threaten the public health.

205. As a direct and proximate result of SoClean's wrongful acts, 3B has been injured and has incurred damages in an amount to be proven at trial.

PRAYER FOR RELIEF

WHEREFORE, 3B prays for judgment as follows:

(A) For an Order and Judgment which:

- i. Preliminarily and permanently enjoins SoClean, its officers, agents, servants and employees, and all persons in active concert and participation with them, including their affiliates, from further disseminating the false and deceptive advertising claims described herein in any form or medium;

- ii. Requires SoClean to withdraw and/or retrieve all offending advertising materials, including the labeling on the packaging for the Product, from the marketplace;
 - iii. Requires SoClean to disseminate among consumers corrective advertising to dispel the false and deceptive messages contained in the subject advertising;
- (B) For an order directing SoClean to account for, and to pay to 3B all gains, profits and advantages derived by SoClean from the above-described wrongful acts;
 - (C) For an award of monetary damages sustained by 3B as a result of SoClean's unlawful conduct, in an amount to be proven at trial; and
 - (D) For an order multiplying or otherwise enhancing any award under paragraphs B and C directly above because of SoClean's willful and deliberate wrongdoing described herein;
 - (E) For an award of punitive damages resulting from SoClean's state law violations in an amount to be proven at trial;
 - (F) For an award of the costs of this action and its reasonable attorneys' fees incurred herein by 3B as authorized by law; and
 - (G) For an award of such other and further relief as this Court deems just and proper.

DEMAND FOR JURY TRIAL

3B respectfully requests a trial by jury on all claims.

DATED: September 13, 2019

Respectfully submitted,

By: /s/Daniel Kotchen
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